



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
[www.uspto.gov](http://www.uspto.gov)

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,303	11/06/2003	Arnold R. Leiboff	461.1008	8007
22846	7590	09/24/2009		
BRIAN ROFFE, ESQ 540-B WILLOW AVENUE CEDARHURST, NY 11516-2211			EXAMINER	
			HALL, DEANNA K	
ART UNIT		PAPER NUMBER		
3767				
MAIL DATE		DELIVERY MODE		
09/24/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/702,303	<b>Applicant(s)</b> LEIBOFF, ARNOLD R.
	<b>Examiner</b> DEANNA K. HALL	<b>Art Unit</b> 3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 11 June 2009.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 7-10,12-14,29 and 31-42 is/are pending in the application.  
 4a) Of the above claim(s) 14, 41 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 7-10, 12-13, 29, 31-40, 42 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 06 November 2003 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____	6) <input type="checkbox"/> Other: _____

**DETAILED ACTION**

***Acknowledgments***

1. This office action is in response to the reply filed on June 11, 2009 where the applicant elected, without traverse, for examination Species II, Claims 31-33 and 35-37. Claims 7-10, 12-13, 29, 34, 38-40 and 42 are generic. Claims 14 and 41 are withdrawn.
2. Claims 7-10, 12-14, 29, 31-42 are pending.
3. Claims 7-10, 12-13, 29, 31-40 and 42 will be examined.
4. The objection to claim 14 is withdrawn (claim is withdrawn).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. **Claims 7-10, 12-13, 29, 31-40 and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hanson et al. (US 5,709,874) ("Hanson") in view of Majlessi (US 4,842,583).**

Hanson discloses a method for positioning a tube in the bowel C4L11-25; comprising:

Pushing a guidewire 28 having a bulbous enlargement 30 at a distal end into the bowel C4L11-25; then sliding an the tube 12 over or along the guidewire such that the guidewire is situated in the passage 20 defined by the tube, Fig. 2.

Hanson discloses the invention as substantially claimed (see above); however, does not directly disclose facilitating passage of the guidewire through the bowel lumen by manipulating the bulbous enlargement from a position alongside and exterior of the bowel by direct pressure or grasping of the bulbous enlargement through intact overlying bowel wall. Majlessi, in the analogous art, teaches grasping and manipulating the bulbous enlargement of the guidewire through intact, exterior bowel wall C3L54-61. Therefore, it would be obvious to combine Hanson and Majlessi because Majlessi discloses a guidewire and irrigation tube in one piece, Hanson is an obvious variant in that in Hanson the guidewire and irrigation tube are separate pieces. It has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

The body cavity of Hanson can be the colon whereby the guidewire would be pushed through the anal sphincter and rectum into the colon C4 L11-25.

The bulbous enlargement of Hanson 30 has a smooth outer arcuate surface Fig. 2 such that the body cavity is not perforated.

Hanson discloses the invention as substantially claimed (see above). However, Hanson does not directly disclose the size of the bulbous enlargement to have a diameter of about 0.25in to about 0.75in. Hanson does disclose that the length and diameter of the tube 12 will vary depending on the body conduit C4 L59-65. Further,

all the figures of Hanson show the guidewire 28 with its bulbous enlargement 30 being sized to fit within the tube 12. Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the size of the tube 12 and thus also the size of the guidewire and bulbous enlargement to correspond to a size appropriate for insertion into the colon. A bulbous enlargement with a size of about 0.25in to about 0.75in would be an appropriate size for insertion into the colon. This sized bulbous enlargement is also taught by Majlessi and guiding the guidewire through the body cavity by manipulating (grasping) the bulbous enlargement and pulling the guidewire outward from the body cavity to compress and shorten the distance between an entrance to the body cavity and a treatment site C3 L54-61. It would be obvious to combine Hanson and Majlessi because Majlessi discloses a guidewire and irrigation tube in one piece Hanson is an obvious variant in that in Hanson the guidewire and irrigation tube are separate pieces. It has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

The tube of Hanson has a distal end 19, a passage 20 and an opening 24 at or near the distal end which communicates with the passage; then directing fluid 25 through the passage defined by the irrigating tube while the irrigating tube is situated over or along the guidewire. See Figs. 2, 9.

***Response to Arguments***

Art Unit: 3767

7. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DEANNA K. HALL whose telephone number is (571)272-2819. The examiner can normally be reached on M-F 9:00am-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3767

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deanna K. Hall/  
Examiner, Art Unit 3767  
9/23/09  
/Kevin C. Sirmons/  
Supervisory Patent Examiner, Art Unit 3767